Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039040 0078 Rev. 00

Manufacturer:

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
USA

Product Category(ies):

Synthetic Bone Graft combined with Biological Origin, Bone Cement, Kyphoplasty Devices, Bone Tamps, Bone Filler Devices, Osteo Introducer Kits, Bone Biopsy Devices, Inflation Syringes, Spinal, Cranial, Dental, and Orthopedic Implants, Sterile Spinal Implants, Sterile Synthetic Bone Substitutes, Sterile Instruments, Cutters, Retractors, Electrical Drive Systems, Electrosurgical Instruments, Endoscopes, Neurological Electrodes, Radio-Frequency Ablation System Generators, Radio Frequency Ablation Systems Including Sterile Probes, Tubing Kits, Pumps, Connectors and Cannulas/Introducers

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72154162

Valid from: 2020-04-27
Valid until: 2024-05-26

Date, 2020-04-27

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany